510(k) Summary MyLab70, 90 Systems Esaote, S.p.A.

SEP 2 5 2008

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Allison Scott
The Anson Group
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Ascott@ansongroup.com

Contact Person:

Allison Scott

Date:

August 12, 2008

807.92(a)(2)

Trade Name:

MyLab70 & MyLab90 Systems

Common Name:

Ultrasound Imaging System

Classification Name(s):

Ultrasonic pulse doppler imaging system 892.1550

Ultrasonic pulsed echo imaging system 892.1560

Classification Number:

90IYN; 90IYO

807.92(a)(3)

Predicate Device(s)

K070106, K062086, K042391, K012564, and K042512	BrainLab	IGSonic
K051308	MyLab70	Esaote, S.p.A.
K051837	MyLab90	Esaote, S.p.A.
K060827	MyLab 70, 90	Esaote, S.p.A.
K013722	RVS	Hitachi

510(k) Summary MyLab70, 90 Systems Esaote, S.p.A.

807.92 (a)(4)

Device Description

The MyLab70 and MyLab90 system designs remain the same as those previously cleared by FDA via K051837, K051308, and K060827, respectively, except for those features being added via this submission.

They are compact ultrasound systems used to perform diagnostic general ultrasound studies. Their primary modes of operation are: B-Mode, M-Mode, Doppler and Color Flow Mapping and, on lower frequency probes and, Tissue Enhancement Imaging (TEI). The systems are equipped with an optional LCD Color Display and can drive phased (PA), convex (CA) and linear array (LA) and Doppler probes.

The MyLab70 and MyLab90 systems are able to produce Real Time 2D images and 3D images (in manual mode) with all probes. The MyLab70 and MyLab90 systems are manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use(s)

Esaote's Model 6150 (MyLab70) and Model 6100 (MyLab90) are mainframe ultrasound systems used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative: Abdominal, and Other: Urologic. Additionally, the MyLab90 is indicated for Laparoscopic use.

The Virtual Navigator is a MyLab optional license that provides additional image information from a second modality like CT or MR, during a clinical ultrasound session. The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the following application: Abdominal, Musculo-skeletal, Urologic, and Vascular.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

510(k) Summary MyLab70, 90 Systems Esaote, S.p.A.

807.92(a)(6)

Technological Characteristics

	Hitachi RVS K013722 Predicate	IGSonic BrainLab K012564 Predicate	Esaote MyLab 90 (6100) K051837	Esaote MyLab 70 (6150) K051308
Virtual Navigator software	YES	YES	To be cleared with this submission	To be cleared with this submission
Primary application	Abdominal	NeuroSurgery	Abdominal, Musculoskeletal Conventional and Superficial, Peripheral Vascular and, Urologic	Abdominal, Musculoskeletal Conventional & Superficial, Peripheral Vascular and, Urologic
Tracking System	Electromagnetic (Ascension)	Optical (NDI)	Electromagnetic (Ascension)	Electromagnetic (Ascension)
Registration Procedure	External Marker – one scan plane	External Marker	External and Internal Marker, one scan plane	External and Internal Marker, one scan plane





Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

SEP 2 5 2008

Esaote, S.p.A. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

Re: K081386

Trade/Device Name: MyLab70 and MyLab90 Systems

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: September 9, 2008 Received: September 10, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the MyLab70 and MyLab90 Systems, as described in your premarket notification:

Transducer Model Number

CA 421	CA 631	LA 523
CA 430	EC 123	LA 532
CA 431	LA 435	PA 122
CA 621	LA 522	PA 230

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all

the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Ms. Lauren Hefner at (240) 276-3666.

Sincerely yours,

Joyce M. Whang, Ph.D.

Acting Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

MWhan

Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K081384
Device Name: MyLab70 and MyLab90 Systems
Indications For Use:
Esaote's Model 6150 (MyLab70) and Model 6100 (MyLab90) are mainframe ultrasound systems used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative: Abdominal, and Other: Urologic. Additionally, the MyLab90 is indicated for Laparoscopic use.
The Virtual Navigator is a MyLab optional license that provides additional image information from a second modality like CT or MR, during a clinical ultrasound session. The second modality provides additional security in assessing the morphology of the ultrasound image.
Virtual Navigator can be used in the following application: Abdominal, Musculo-skeletal, Urologic, and Vascular.
The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.
The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.
Prescription UseX AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices 8/386

510(k) Number

MyLab90 & 70XVG

	_					Mode of	Mode of Operations				
Clinical Application	6	Σ	PWD	CWD	Color Doppler	Amplitude	Combined [4]	Color Velocity	Tissue	E 5	Other (specify)
-11						Copplet		Mapping (IVM) K051837	Enhacement Imaging (TEI)	K051837	
Ophthalmic						-					
Fetal			٩		٩	a	٩	0			
	KO51837	K051837	K051837	K051837	K051837	K051837	K051837	/spfgny	KO51837	K051837	6, 7, 8, 9, 12
Abdomina	P 700	4	P .	d	a	۵	a.	Р КО51837	d	a.	6, 7, 8, 9, 12, 13
Intraoperative (Abdominal)	POTCON	, 18183/	AUS183/	K051837	K051837	K051837	KO51837	1	K051837	K051837	
	K051837	K051837	K051837	K051837	P K051837	P KO51837	p YESTESTY	P K051837	q	P P	6, 8, 9, 12, 13
Intraoperative Neurological									122	VEB1EAN	
Pediatric	_	_	۵	ļ.				7E41307			
	K051837	K051837	K051837	K051837	K051837	K051837	K051837		K051837	K051837	6, 7, 8, 9, 12, 13
Small Organ [1]	<u>.</u>	<u>.</u>	Α.	4	4	۵	ď	P K051837	۵	-	6, 8, 9, 12, 13
Name of the state	K051837	K051837	K051837	K051837	K051837	K051837	K051837		KO51837	K051837	
	K051837	P K051837	KO51837	F KO51837	4051837	P K051837	P K051837	P K051837	p 9	P P	6, 8, 9, 12
Adult Cephalic	۵	٩	٩						YEST EN	/ COT CON	
	K051837	K051837	K051837	K051837	KO51837	K051837	K051837	r K051837	K051837	P K051817	6, 8, 9, 12
Cardiac [2] (MtF369)	4	a	۵			۵	a	P K051837	-		57 8 9 17
	K051837	K051837	X051837	K051837	KO51837	KO51837	K051837		K051837	K051837	71 '5' 9' 17
ransesophageal (Cardiac)	4	۵.	۵.	4.	۵			P K051837	۵	4	6, 8, 9, 12
2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	KO51837	K051837	K051837	K051837	K051837	K051837	K051837		K051837	K051837	
Iransesopnageal (Non Cardiac)											
Transrectal	P KOK1892	9	P P P P P P P P P P P P P P P P P P P	d.	9		a !	P K051837		۵	6, 8, 9, 12, 13
Transvagina		d) care	/601COV	NOST837	KU5183/	KU51837	İ	K051837	K051837	
	K051837	¥051837	K051837	K051837	K051837	K051837	K051837	/ KUS183/	VCE1827	P 2023	6, 8, 9, 12
Transurethrai										/50Tcou	
Intravascular											
Periphera! Vascular	a.	•	_		_	۵	4.	P K051837	a		6 7 8 9 12 13 14
	K051.837	K051837	K051837	K051837	K051837	KO51837	KO51837		K051837	K051837	
Laparoscopic	ء ا	<u>.</u>	۵	•	۵		<u>-</u>	P . K051837		_	6, 8, 9, 12
	KUS1847	K051837	K051837	K051837	K051837	K051837	K051B37		K051837	K051837	
Musculo-skeleta: Conventional [3]	F F KOS 1837	P V051837	P P	roc1 022	4 303	- L	4	4 (50X d	Ь		6, 8, 9, 12, 13
Miscrido-chalatal Suppression (3)		rerow c) carrow	VC0102V	/681cm	KUS1847	KD51837		*051837	K051837	
MOSCONO-SAGISCAL SUPERINGE [3]	K051837	FO51837	KM5.1847	rus 1837	P P P P P P P P P P P P P P P P P P P	4 503	Q 2	P K051837	4	٠.	6, 8, 9, 12, 13
Other (Urological)	۵	۵	٩			COTCON) COTTO		KU51837	K051837	
(K051837	K051837	KD51837	K051837	K051837	K051837	K051837	F K051837	P P P P P P P P P P P P P P P P P P P	F061037	6, 7, 8, 9, 12, 13
N = New: P = Previously Cleared by FDA									COLUMN TO A	1001001	

N = New; P = Previously Cleared by FDA

[8] VPan k051837 & MtF374 [9] XView K051837 [4] Combined [6] 3D k060827 & MtF369 [1] Small Organs Includes Breast, Thyroid and Testicles [2] Cardiac is Adult and Pediatric

[7] 4D k060827 & MtF369 [3] Musculo Skeletaí includes Nerve Block Mt£377

Concurrence of CDRH, Office of Device Evaluation (ODE)

[14] IMT MtF374

[13] TP-View MtF374

[12] Compound k051837

(Division Sign-Off) UV Boominal and Division of Reproductive, Abdominal and Radiological Devices \$10(k) Number

						Mo	Mode of Operations	ions			
Clinical Application	6	Σ	DWP	CWD	Color Doppler	Amplitude	Combined [4]	Color Velocity	Tissue Enhacement Imaging	CnTl	Other
	-					Doppler		Mapping (TVM)	(TEI)		(specify)
Ophthalmic											
Fetal	P K051837	P K051837	P K051837		P KUS1837	p 9	q		P K051837	d	6, 8, 9, 12
Abdominal	<u> </u>	<u>a.</u>	_		a.	d	d d	3	P K051837	K051837	0 0 17
intranscrating (Abd age) - 11	K051837	K051837	K051837		KD51837	K0S1837	K051837			K051837	71 'E 'a 'b
and appealance (Andominal)											
Intraoperative Neurological											
Pediatric	_				4	Δ.				a	
	K051837	K051837	K051837		K051837	K051837	K051837			X051837	b, 8, 9, 12
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Adult Cephalic							 				
Transesophageal (Non Cardiac)						ļ.					
Transrectal					-						
Transvagina			İ								
ransvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P K051837	P 7051037	P		a.	۵			P K051837	۵	6, 8, 9, 12
Laparoscopic		TOYCON	NUSTESS /		K051837	K051837	K051837			K051837	
Musculo-skeletal Communicaci (2)	٩	-	ľ								
	MtF374	MtF374	MtF374		P MdfE374	P NA+E374	Р		P MtF374	۵	6.8,9,12
Musculo-skeletal Superficial (3)	-	a	١		100	2/2	INICES/4			MtF374	
	MtF374	MtF374	MtF374		MtF374	MtE374	р М+£37л		P MtF374	a.	6,8,9,12
Other (Urological)	_	a	4		٩		A			MtF3/4	
	K051837	K051837	K051837		K051837	K051837	K051837		/ KU5183/	P K051837	6, 8, 9, 12
N = New: P = Previously Cleared In: CDA											

N = New; P = Previously Cleared by FDA

[8] VPan - MTF 374

[3] Musculoskeletal - Nerve Block

[4] Combined modes are:B+M+PW+CFM+PD

[9] XView - K051837

[12] Compound K051837

[6] 3D K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices 286 510(k) Number

						Mod	Mode of Operations	suo			
Clinical Application	æ	Σ	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Calor Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P K051837	P K051837	F K051837		P K051837	P K051837	P K051837		P K051837	P K051837	6, 8, 9, 12
Abdominal	P K051837	P K051837	P K051837		P K051837	P K051837	P K051837		р қо51837	P K051837	6, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	p MFE 374	P M#E374	P P P P P P P P P P P P P P P P P P P		P P P P P P P P P P P P P P P P P P P	P M+E374	P P A4+E37A		P MtF374	P	6,8,9,12
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Adult Cephalic											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											!
Transurethral											
Intravascular											
Peripheral Vascular	P K051837	P K051837	P K051837		P KOS1837	P K051837	P K051837		P K051837	P K051837	6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]	P MtF374	р МtF374	P MtF374		р МтF374	P MtF374	Р МtF374		P MtF374	P MtF374	6,8,9,12
Musculo-skeletal Superficial [3]	P MtF374	P MtF374	P MtF374		P NtF374	P MtF374	P MtF374		P MtF374	P MtF374	6,8,9,12
Other (Urological)	P MtF374	P MtF374	P MtF374		P MtF374	P MtF374	P MtF374		p MtF374	P MtF374	6,8,9,12
N = New; P = Previously Cleared by FDA											

[3] Musculoskeletal - Nerve Block

[4] Combined modes are:B+M+PW+CFM+PD [6] 3D K051837

[8] VPan - MTF 374

[9] XView - KD51837 [12] Compound K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) \mathcal{V} (Division of Reproductive, Abdominal and Radiological Devices KOSI 386 510(k) Number

						Mod	Mode of Operations	suc			
Clinical Application	an.	₽	PwD	CWD	Cotor Doppler	Amplitude	Combined [4]	Color Velocity	Tissue Enhacement Imaging	CnTI	Other
Ophthalmic						2		fix and draw	(12.1)		(Alicade)
Feta!	P MtF329	P MtF329	P Mr£379		P	P P	P M+6279		P MtF329	d preday	6'8'9
Abdominal	P P	P P	d d		P P	d.	д.		P MtF329	a	6,8,9
Intraoperative (Abdominal)					CZC JNAL	(AR.F.32.3	FZC-JNIN			WIT-329	
Intraoperative Neurological											
Pediatric	P MtF329	P MtF329	P MtF329		P MtF329	P M#F329	P M*F329		P MtF329		6'8'9
Small Organ [1]											:
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Adult Cephalic											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	a.	a.	_		۵	a.	۵		P MtF329	۵	6,8,9
	MtF329	MtF329	MtF329		MtF329	MtF329	MtF329			MtF329	
Laparoscopic											
Musculo-skeletal Conventional [3]	ط	a.	۵		۵	a	۵		P MtF329	۵	6,8,9
	MtF329	MtF329	MtF329		MtF329 ·	MtF329	MtF329			MtF329	
Musculo-skeletal Superficial [3]	a.	4	d		_	_	4		P Mtf329	a	6,8,9
	MtF329	MtF329	MtF329		MtF329	MtF329	MtF329			MtF329	
Other (Urological)	a.	Δ.	d			a.	۵		P MtF329		6,8,9
	MtF329	MtF329	MtF329		MtF329	MtF329	MtF329				
N = New: P = Previously Cleared by FDA											

N = New; P = Previously Cleared by FDA

[3] Musculoskeletal - Nerve Block

[4] Combined modes are:B+M+PW+CFM+PD [6] 3D K051837

[9] XVIew - K051837

[8] VPan · MTF 374

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

						Mod	Mode of Operations	US			
Clinical Application	an a	Σ	PWD	Cwo	Color Doppler	Amplitude	Combined [4]	Calar Velocity	Fissue Enhacement Imaging	CnTI	Other
						Doppler		Mapping (TVM)	(TEI)		(specify)
Ophthalmic											
Fetal	۵	۵	a.		۵	_	n.		P K051837	۵	6, 8, 9, 12
	K051837	KD51837	KD51837		K051837	K051837	K051837			K051837	;
Abdominal		a. ·	a.		d	۵	4		P K051837	۵	6, 8, 9, 12
	K051837	K051837	K051837		K051837	K051837	K051837			K051837	
Intraoperative (Abdominal)											
intraoperative Neurological											
Pediatric	P MtF374	P MtF374	P. MtF374		P MtF374	P MtF374P	P MtF374		P MtF374	P MtF374	6,8,9,12
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Adult Cephalic											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P K051837	Р КФ51837	P KD51837		P K051837	P K051837	P K051837		P K051837	р КО51837	6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]	P MtF374	P MtF374	P MtF374	!	P MtF374	p MtF374 P	P MtF374		P MtF374	P WtF374	6,8,9,12
Musculo-skeletal Superficial [3]	P MtF374	P MtF374	P MtF374		P MtF374P	P MtF374 P	P MtF374		P MtE374	Р МtF374	6,8,9.12
Other (Uralogical)	P 7007	9 7581937	q 7		q 4	P 700,000	p 7001307		P KD51837	P 7051937	6, 8, 9, 12
	/cgTcnv	YESTEN'S	(027gg)		/ FOTENA	/soreny	/corcov			1007004	

N = New; P = Previously Cleared by FDA

[3] Musculoskeletai - Nerve Block [4] Combined modes are:B+M+PW+CFM+PD

[6] 3D K051837

[8] VPan - MTF 374 [9] XView - K051837

[12] Compound K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) u "Division of Reproductive, Abdominal and

K081386 Radiological Devices 510(k) Number

						Mod	Mode of Operations	80			
Clinical Application	<u>.</u>	Σ	PwD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	Р	p MrE369	р		q parata	P 94+C3-60	Р		P MtF369	P 04+6360	6,8,9
Shormiss	-				Car IIIII	one num	25.11		p MAFFE	COC NIL	6 8 9
Apacinina	MtF369	MtF369	M#F369		MtF369	MtF369	r MtF369			r MtF369	n 'o 'o
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	р МtF369	P MtF369	P MtF369		P MtF369	P MtF369	P MtF369		P MtF369	р МtF369	
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Adult Cephalic											
Transesophageal (Non Cardiac)											
Transrectal								-			
Fransvaginal											
Transurethral										E	
Intravascular											
Peripheral Vascular	P MtF369	P MtF369	9 MtF369		69E37WI	P MtF369	p MtF369		69EJ1W d	P MtF369	6,8,9
Laparoscopic											
Musculo-skeletal Conventional [3]	P MtF369	P MtF369	69E3IW		p MtF369	р МtF369	P MtF369		P MtF369	P MtF369	6'8'9
Musculo-skeletal Superficial [3]	۵	۵	۵		d	Ы	d.		P MtF369	۵	6,8,9
	MtF369	MtF369	MtF369		MtF369	MtF369	MtF369			MtF369	
Other (Urological)	۵	đ	Ь		ď	Ь	Ь		P MtF369		6,8,9
	MtF369	MtF369	MtF369		MtF369	MtF369	MtF369				
N = New: D = Previously Cleared by FDA	VU.										

N = New; P = Previously Cleared by FDA

[3] Musculoskeletal - Nerve Block [4] Combined modes are: B+M+PW+CFM+PD [6] 3D K051837

[8] VPan - MTF 374

[9] XView - K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal and Radiological Devices $\mathcal{Los}(386)$ (Division Sign-Off)

						Mode o	Mode of Operations				
Clinical Application	86	Σ	PWD	CWD	Color Doppler	Amplitude	Combined [4]	Color Velocity Manning (TVM)	Tissue Enhacement	CnTl	Other
	···········					1			/) 6		/Augade)
Ophthalmic											
Fetal	٩ -	۵ إ	d		۵	٥	a		р ко51837	a.	6, 8, 9, 12
	K051837	K051837	K051837		K051837	K051837	K051837			K051837	
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological								:			
Pediatric											
Small Organ [1]											
Neonatal Cephalic										•	
Adult Cephalic											
Cardiac [2]											
Adult Cephalic											
Transesophageal (Non Cardiac)											
Transrectal	P K051837	k051837	P K051837		P K051837	P K051837	P K051837		Р К051837	P K051837	6, 8, 9, 12
Transvaginal	P K051837	P K051837	р К051837		P K051837	P K051837	P K051837		р КО51837	P K051837	6, 8, 9, 12
Transurethral		L									
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	d.	ď	Ь		۵.	a.	۵		P K051837	d	6, 8, 9, 12
	K051837	K051837	K051837		K051837	K051837	K051837			K051837	
A Charles of Cartes and a Charles of the Charles of											

N = New; P = Previously Cleared by FDA

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D K051837

[8] VPan - MTF 374

[9] XView - K051837

[12] Compound - K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) V'' Division of Reproductive, Abdominal and

Radiological Devices μ_{OS138} C 510(k) Number

					İ	Mode	Mode of Operations	ns.	:		
Clinical Application	89	×	DWM	CWD	Color Doppler	Amplitude	Combined [4]	Color Velocity	Tissue Enhacement Imaging	ĒΩ	Other
						Doppler		Mapping (TVM)	(TEI)	_	(specify)
Ophthalmic			_								
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P MtF329	P MtF329	P MtF329		P MtF329	P Mtf329	р МtF329		P MTF 329		6, 8, 9, 13
Small Organ [1]	М1F329	P MtF329	P MtF329		P MtF329	P MtF329	P MtF329		P MTF 329		6, 8, 9, 13
Neonatal Cephalic											
Adult Cephalic	L										
Cardiac [2]											
Adult Cephalic			 								
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral					-						
Intravascular											
Peripheral Vascular	р МtF329	P MtF329	р МtF329		p MtF329	P MtF329	P MtF329		p MTF 329		6, 8, 9, 13
Laparoscopic											
Musculo-skeletal Conventional [3]	P MtF329	P MtF329	р Мt£329		P MtF329	P MtF329	р МtF329		P MTF 329		6, 8, 9, 13
Musculo-skeletal Superficial [3]	р М1F329	P MtF329	p MtF329		P MtF329	р МtF329	P MtF329		P MTF 329		6, 8, 9, 13
Other (Urological)											

N = New; P = Previously Cleared by FDA

d [6] 3D MTF 374

[13] TP-View - MTF 374

 Small Organs includes Breast, Thyroid and Testicles

ck [8] VPan - MTF 374 [9] XView - MTF329

(3) Musculoskeletal - Nerve Block [4] Combined modes are: B+M+PW+CFM+PD

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices $\angle 08/386$

					!	Mode	Mode of Operations	su			
Clinical Application	8	Σ	PWD	CWD	Color Doppler	Ampiitude	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other
Ophthalmic											((,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P K051837	P K051837	P K051837		P K051837	р КО51837	P K051837		P K051837	P KD51837	6, 8, 9, 12, 13
Small Organ [1]	P X051837	P K051837	P K051837		P K051837	р КО51837	P K051837		Р КО51837	P K051837	6, 8, 9, 12, 13
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Adult Cephalic									-		
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P K051837	P K051837	р КО51837		P K051837	F K051837	P K051837		P K051837	P K051837	6, 8, 9, 12, 13, 14
Laparoscopic											
Musculo-skeletal Conventional [3]	P K051837	P KD51837	р К0S1837		P K051837	P KD51837	P K051837		P K051837	P KO51837	6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	P K051837	P K051837	Р К051837		Р КО51837	P K051837	P K051837	:	P K051837	P K051837	6, 8, 9, 12, 13
Other (Urological)											
N = New; P = Previously Cleared by FDA	y FDA										

[8] VPan - MTF 374 [1] Small Organs includes Breast, Thyroid and Testicles

[9] XView - K051837 [2] Cardiac is Adult and Pediatric

[12] Compound - K051837 [13] TP-View -MTF 374 [3] Musculoskeletal - Nerve Block [4] Combined modes are: B+M+PW+CFM+PD

IGI 3D - KO60827 & MTF 369 (14) IMT -MTF 374 Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal and Radiological Devices 510(k) Number (Division Sign-Off)

16081386

Clinical Application B M PWD CWD Color Doppled Amplitude Combined (4) Color Velocity Tissue Enhacement Cnit Checkular Checkular Amplitude Combined (4) Color Velocity Tissue Enhacement Color Velocity Redunda Abdorniaal Amplitude Color Velocity Tissue Enhacement Color Velocity Redunda Abdorniaal Color Velocity Color Velocity Tissue Enhacement Color Velocity Redundit Abdorniaal Color Sasa Color							Mode	Mode of Operations	i mi			
	Clinical Application	6	Σ	QWq		Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Mon Cardiard Mon Cardiard	Ophthalmic											
According Acco	Fetal											
MonCardiac P	Abdominal											
Mon Cardiac P	Intraoperative (Abdominal)	ļ										
Non Cardiar Nos. 1837 N	Intraoperative Neurological										5	
Non Cardiac) P P P P P P COS1837 COS1837 COS1837 P P COS1837 P P COS1837 COS	Pediatric	P K051837	P K051837	P K051837		P K051837	P K051837	P KD51837			P K051837	6, 8, 9, 12, 13
Non Cardiac) Non Cardiac) Processor	Small Organ [1]	P K051837	P K051837	P K0S1837		P KD51837	P KO51837	P K051837		۵	P K051837	6, 8, 9, 12, 13
Non Cardiac) P P P P P Conventional [3] P<	Neonatal Cephalic											
Non Cardiac) P P P P P Conventional [3] P P P P P P P P ROS1837 COS1837	Adult Cephalic											
Non Cardiac) P <t< td=""><td>Cardiac [2]</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<>	Cardiac [2]											
Non Cardiac) Non Cardiac) Non Cardiac) Non Cardiac) Non Cardiacia Non Cardiaci	Adult Cephalic											
r	Transesophageal (Non Cardiac)											
F	Transrectal											
Interference of the final [3] P	Transvaginal											
F	Transurethral						:					-
r p p p p p p kO51837 KO51837 KO51837 KO51837 KO51837 KO51837 P P KO51837 RO51837 RO	Intravascular											
Conventional [3] P P P P P P P KOS1837 KOS1837 KOS1837 KOS1837 KOS1837 KOS1837 KOS1837 P ROS1837 ROS1837 ROS1837 P ROS1837 ROS1837 ROS1837 P ROS1837 ROS1837 <th< td=""><td>Peripheral Vascular</td><td>P K051837</td><td>P K051837</td><td>р КО51837</td><td></td><td>P K051837</td><td>P K051837</td><td>P K051837</td><td></td><td></td><td>Р КО51837</td><td>6, 8, 9, 12, 13, 14</td></th<>	Peripheral Vascular	P K051837	P K051837	р КО51837		P K051837	P K051837	P K051837			Р КО51837	6, 8, 9, 12, 13, 14
Conventional [3] P P P P P K051837 K051837 K051837 P P K051837 inperficial [3] P P P P P P R051837 R051837 P R051837 R051837 P R051837 R0	Laparoscopic											
inperficial [3] P P P P F P KOS1837 KOS1837 KOS1837 KOS1837 ROS1837 P ROS1837	Musculo-skeletal Conventional [3]	P K051837	P K051837	P K051837		P K051837	P KD51837	P K051837			P K051837	6, 8, 9, 12, 13
TOTTON TOTTON TOTTON TOTTON	Musculo-skeletal Superficial [3]	P V0C1827	P V051923	P 7		Proct207	P 70512037	P 7051937			P 7051037	6, 8, 9, 12, 13
Onies (cronolities)	Contract of the Contract of th	200	-		Ī	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					COTON	
	Other (Oronogical)						_					

[6] 3D KO51837

[13] TP-View - MTF 374

[14] IMT -MTF 374

[1] Small Organs includes Breast, Thyroid and Testicles

(9) XView - K051837 [8] VPan - MTF 374 [3] Musculoskeletal - Nerve Block [2] Cardiac is Adult and Pediatric

[4] Combined modes are: B+M+PW+CFM+PD

Concurrence of CDRH, Office of Device Evaluation (ODE)

[12] Compound - K051837

Division of Reproductive, Abdominal and (Division Sign-Off) Radiological Devices 510(k) Number

K081386

						Mo	Mode of Operations	ions			
Clinical Application	80	Σ	DWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)		٠									
Intraoperative Neurological											
Pediatric	P K051837	P K051837	P K051837		Р К051837	P K051837	р К051837		Р КО51837	Р КО51837	6, 8, 9, 12, 13
Small Organ [1]	P K051837	р КОS1837	P KO51837		р К051837	Р К051837	P K051837		P K051837	р К051837	6, 8, 9, 12, 13
Neonatal Cephalic											
Adult Cephalic	!										
Cardiac [2]											
Adult Cephalic											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal									-		
Transurethral											
Intravascular									İ		
Peripheral Vascular	P K051837	Р КО51837	р КО51837		P K051837	P KD51837	P K051837		P K051837	Р К051837	6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional [3]	P MtF369	P MtF369	р МtF369		p MtF369	P MtF369	P MtF369		P MtF369		6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]											
Other (Urological)											
N = New; P = Previously Cleared by FDA	y FDA										

[8] VPan - MTF 374 [1] Small Organs includes Breast, Thyroid

[3] Musculoskeletal - Nerve Block and Testicles

[12] Compound - K051837 [9] XView - K051837 [4] Combined modes are:

[13] TP-View - MTF 374 B+M+PW+CFM+PD [6] 3D K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal and (Division Sign-Off)

Radiological Devices 510(k) Number

MyLab90 & 70XVG-PA122

						Moc	Mode of Operations	ons			
Clinical Application	8	×	QMd	CWD	Color Doppler	Amplitude	Combined [4]	Color Velocity	Tissue Enhacement Imaging	: CnTI	Other
						Doppler		Mapping (TVM)	(TEI)		(specifγ)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P K051837	P KDS1837	P K0S1837	P .	р KOS1837	P K051837	р КО51837	P K051837	P K051837	P K051837	6, 8, 9, 12
Small Organ [1]											
Neonatal Cephalic	P +	P K051837	P X051837	P KOS1837	P KO51837	P K051837	P KO51837	p K051837	P K051837	P K051837	6, 8, 9, 12
Adult Cephalic					F			:			
Cardiac [2]	P K051837	P K051837	P X051837	P KOS1837	P KOS1837	P K051837	P K051837	P K051837	P K051837	P K051837	6, 8, 9, 12
Adult Cephalic											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	Р КО51837	P KD51837	P K051837	Р КО51837	р КО51837	Р КО51837	р КО51837	P K051837	P K051837	P KD51837	6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)									-		
ACT and Learner of the Control of th	ž										

N = New; P = Previously Cleared by FDA

[6] 3D K060827 & MTF 36: [1] Small Organs includes Breast, Thyroid

[8] VPan MTF 374 [2] Cardiac is Adult and Pediatric

[12] Campound K051837 [9] XView K051837 [3] Musculoskeletal - Nerve Block [4] Combined modes are: B+M+PW+CW+CFM+PD

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal and Radiological Devices 510(k) Number (Division Sign-Off)

MyLab90 & XVG - PA230

						Moć	Mode of Operations	ons				
Clinical Application	8	Σ	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)		Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
						:		-				
Ophthalmic												
Fetal												
Abdominal	P V051937	P */051837	P 7681203	P #051837	P 7	P V051937	م 1927ع	P K051837	37 р	K051837	P P	6, 8, 9, 12
Intraoperative (Abdominal)		, careau	1000	2000	(2012)	7004700	CONTON				/507500	
Intraoperative Neurological												
Pediatric												
Small Organ [1]												
Neonatal Cephalic												
Adult Cephalic	_	_	4	G.		۵.	۵	P K051837	37 р	K051837	a	6, 8, 9, 12
***************************************	K051837	KD51837	K051837	K051837	K051837	K051837	K051837				K051837	
Cardiac [2]	۵	Ь	۵	a.	a.	a	Ь	P K051837	37 P	K051837	۵	6, 8, 9, 12
	K051837	K051837	K051837	KD51837	K051837	K051837	K051837				K051837	
Adult Cephalic												
Transesophageal (Non Cardiac)												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	P MTF369	P MTF369	P MTF369	P MTF369	P MTF369	P MTF369	P MTF369	P MTF369	d 6:	MTF369	P MTF369	6, 8, 9, 12
Laparoscopic												
Musculo-skeletal Conventional [3]												
Musculo-skeletal Superficial [3]												
Other (Urological)												

N = New; P = Previously Cleared by FDA

[6] 3D K060827 & MTF 369 [1] Small Organs includes Breast, Thyroid

[2] Cardiac is Adult and Pediatric and Testicles

[9] XView K051837 [8] VPan MTF 374

[3] Musculoskeletal - Nerve Block

[12] Compound K051837

[4] Combined modes are: B+M+PW+CW+CFM+PD

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal and Radiological Devices $\mathcal{LOS}/\mathcal{SSE}$ (Division Sign-Off)

MyLab70

Compact politication B							ļ						
Majoriety (TVA) Color Color Combined (A) Color (Morey) Color (More				!			Mode c	of Operations	m.				
Continue Continue	Clinical Application	B	ž	PWD	CWD	Color	Amplitude	Combined [4]	Color	Velocity	Tissue	CnTI	Other
CKC512006 KKC512008 KKC5		_				Doppler	Doppler (PD)		Mappi	ng (TVM)	Enhacement	k052805 &	(specify)
									K052805	& MtF323	Imaging (TEI) MtF323	MtF323	
KOST308	Ophthalmic												
KOS1308 KOS1	Fetal	Δ.	a	۵	۵	Ь	d .	d	۵	K052805			5, 6, 7, 8, 9, 12.
KOS1308 KOS1		K051308	X051308	K051308	K051308	K051308	K051308	K051308				KU328U3	
Mostage Most	Abdominal	K051308	P KD51308	P KDS1308	P *051308	P K051308	P K051308	P K051308	4	K052805		P K052805	5, 6, 7, 8, 9, 12, 13
KOS1308 KOS1	intraoperative (Abdominal)	۵	۵	۵		۵	۵	d	1	K052805		ļ.,	6, 8, 9, 12, 13
KOS1308 KOS1		K052805	K052805	K052805		K052805	K052805	K052B05				K052805	
KOS1308 COS1308 COS1308 <t< td=""><td>Intraoperative Neurological</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<>	Intraoperative Neurological												
KOS1308 KOS1308 KOS1308 KOS1308 KOS1308 KOS1308 KOS1308 KOS1308 KOS1308 KOS1309 KOS1	Pediatric	۵	۵	ď	۵.	۵.	<u> </u>	D.	D.	K052805			5, 6, 7, 8, 9, 12,
KOS1308 KOS1		K051308	KD51308	K051308	K051308	K051,308	K051308	K05130B				4	13
KOS1308 KOS1	Small Organ [1]	•	۵		a.	۵.	ů.	D.	۵.	K052805			5, 6, 7, 8, 9, 12,
KOS1308 KOS1		K051308				4	13						
KOS1308 KOS1	Neonatal Cephalic	P K051308	P K051308	P K051308	P K051308	P K051308	P K051308	P KOS1308	<u>. </u>	K052805			5, 6, 8, 9, 12
KOS1308 KOS1308 <t< td=""><td>Adult Cephalic (MtF346)</td><td>۵</td><td>۵</td><td>a.</td><td>4</td><td>۵</td><td>۵</td><td>a.</td><td>۵</td><td>K052805</td><td></td><td></td><td>5, 6, 9, 12</td></t<>	Adult Cephalic (MtF346)	۵	۵	a.	4	۵	۵	a.	۵	K052805			5, 6, 9, 12
Mostage Most	-	K051308	K051308	K051308	K051308	K051308	K051308	KOS1308				_	
KOS1308 KOS1	Cardiac [2] (MtF356)	۵	d	a.	Ь	Ь	Ь	d	Ь	K052805			5, 6, 7, 8, 9, 12
Heary For the continue For		K051308	K051308	KD51308	K051308	K051308	K051308	K051308				_	
Horizon Koostagoa Koosta	Transesophageal (Cardiac)	۵.	n.	4	Ь	Ь	Ь	Δ.	<u>.</u>	KD52805			5, 6, 9, 12
		K051308	KDS1308	KD51308	K051308	K051308	K051308	K051308				K052805	
KOS1308 P P KOS1308 ROS1308 KOS1308 KO	Transesophageal (Non Cardiac)												
KOS1308 KOS1308 <t< td=""><td>Transrectal</td><td>۵</td><td>D.</td><td>a</td><td></td><td>۵</td><td>a.</td><td>۵.</td><td>_</td><td>KD52805</td><td></td><td></td><td>5, 6, 8, 9, 12, 13</td></t<>	Transrectal	۵	D.	a		۵	a.	۵.	_	KD52805			5, 6, 8, 9, 12, 13
KOS1308 KOS1		K051308	K051308	K051308		K051308	K051308	K051308				K052805	
NOSI308 NOSI	Transvaginal	q	4 5	q 500		d 200	g 200	P 7051270	D.	K052805		P	5, 6, 8, 9, 12
No. P	Transfer	ROSTSON	POSTERN	NOSTSON		DOCTTON.	COLLEGA	and took				2007	
Model Mode	Cotravaccular												
MOSI 308 KOSI 308	Perinheral Vaccular	_	٩	-	_	_	<u>a</u>	۵	_	K052805		L	5, 6, 7, 8, 9, 12,
Onal [3] P P P P P P KO52805 P P RO52805 P RO51308 P </td <td></td> <td>K051308</td> <td>K051308</td> <td>K051308</td> <td>K051308</td> <td>K051308</td> <td>K051308</td> <td>K051308</td> <td></td> <td></td> <td></td> <td>K052805</td> <td>13, 14</td>		K051308				K052805	13, 14						
Orial [3] P P P P NG52805 P KO51308 P P RO52805 P RO51308 P P RO52805 P RO51308 P RO52805 RO52805 P RO52805 </td <td>taparoscopic</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>_</td> <td></td> <td></td> <td></td> <td></td>	taparoscopic								_				
KOS1308 KOS1	Musculo-skeletal Conventional [3]	<u>.</u>	α.	۵.	۵.	o.	۵.	۵	۵.	K052805			5, 6, 7, 8, 9, 12,
KOS1308 KOS1		K051308				_	13						
KOS1308 KOS1308 <t< td=""><td>Musculo-skeletał Superficial [3]</td><td>۵</td><td>a.</td><td>a.</td><td>_</td><td>a.</td><td>۵</td><td>۵</td><td><u>-</u></td><td>K052805</td><td></td><td></td><td>5, 6, 7, 8, 9, 12,</td></t<>	Musculo-skeletał Superficial [3]	۵	a.	a .	_	a.	۵	۵	<u>-</u>	K052805			5, 6, 7, 8, 9, 12,
p p		K051308	K051308	K051308	K0513D8	K051308	K051308	K051308				_	13
K0513Q8 K0513Q8 K0513Q8 K0513Q8 K0513Q8 K0513Q8	Other (Urological)	۵	a.	a .	۵	a.	۵	۵.	_	K052805			5, 6, 7, 8, 9, 12,
		K051308				K052805	13						

N = New; P = Previously Cleared by FDA [1] Small Organs includes Breast, Thyroid and

[2] Cardiac is Adult and Pediatric

[7] 4D k060827 MtF356

[6] 3D k060827

[3] Musculo Skeletal - Nerve Block- k071996

[4] Combined modes are: B+M+PW+CW+CFM+PD [5] CMM k052805

[8] VPan KO52805, MtF323 & 374 [9] XView MtF336 [10] Stress k051308

Concurrence of CDRH, Office of Device Evaluation (ODE)

[11] Xstrain k060827

[12] Compound Imaging - K052805 [13] TP-View - MTF#374

[14] IMT - MTF#331 & 374

[15] Automatic Gain - MTF#374

(Division Sign-Off) /// Division of Reproductive, Abdominal and Radiological Devices Ko11386

						 							
					;	ow	mode of Operations	SUOI					
Clinical Application	æ	Σ	PWD	CWD	Color Doppler	Amplitude Dappler	Combined [4]	Color Mappir	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	ging CnTI		Other (specify)
												_	
Ophthalmic						·						-	
Feta!	P K051308	P KDS1308	P K051308		P K051308	P K051308	р К051308	a.	MtF323	P K051308	P MtF323	23	6,8,9
Abdominal	P K051308	P K051308	P K051308		р К051308	P K051308	P KD513D8	a.	MtF323	P K051308	P MtF323	23	6,8,9
Intraoperative (Abdominal)													
Intraoperative Neurological								-					
Pediatric	P KDS1308	P K051308	Р К051308		P K051308	р К051308	Р КО51308	ф	MtF323	P K051308	P MtF323	123	6, 8, 9
Small Organ [1]													
Neonatal Cephalic											_	1	
Adult Cephalic												+	
Cardiac [2]												-	
Transesophageal (Cardiac)												+	
Transesophageal (Non Cardiac)												+	
Transrectal												\dashv	
Transvaginal												-	
Transurethral													
Intravascular													
Peripheral Vascular	P K051308	4 K051308	P K051308		р КО51308	Р КО51308	р К051308	a.	MtF323	P K051308	P MtF323	123	e, 8, 9
Laparoscopic											-		
Musculo-skeletal Conventional [3]	Р	d d	d d		d d	P PA+E356	p M+E356			P MtF356			6,8,9
	INKESSO	1011230	INIT 230		200	Oct IVI	2			0000000			000
Musculo-skeletal Superficial [3]	P MtF356	P MtF356	P MtF356	. —	P Mtf356	P MtF356	MtF356						n 'a 'a
Other (Urological)	P K051308	P K051308	P KDS1308		P K051308	P K051308	P K051308	a.	MtF323	P K051308	P MtF323	123	6,8,9
	The street of the street												

N = New; P = Previously Cleared by FDA

[3] Musculo Skeletal - Nerve Block [4] Combined modes are: B+M+PW+CFM+PD

[6] 3D - MTF 356

[8] VPan - MTF 323 [9] XView - MTF 336

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) f (Type 1777) f (Division of Reproductive, Abdominal and Radiological Devices f (k) Number f (k) Number

Clinical Application B M Ophthalmic P P P Fetal K051308 K051308 K051308 Abdominal P P P Intraoperative (Abdominal) K051308 K051308 Intraoperative Neurological P P Pediatric P P Small Organ [1] MME347 ME347 Monatal Carbalic Macontal Carbalic Mematal			CWD Col	Color Doppler	Amplitude	ude Combined [4]	Color Velocity	Tissue Enhacement Imaging	CnTI	100
P				or Doppier		Compined [4]	COID! VEIOULLY	Builden making	=======================================	
K051308 K051308 Abdominal) Veurological P P MXE347		,			Doppler		Mapping (TVM)	(TEI)		(specify)
K051308 K051308 Abdominal) Reurological P MRE347		١								
Abdominal) Reurological P MtE347	+	F		P K051308	P K051308	P / K051308		P K051308		6,8,9
kos1308 Abdominal) leurological P MtF347		POCTON		2004	nort-ou	POCTON!			1	0
Abdominal) leurological p MtF347	+	P K051308		P K051308	P K051308	P K051308		P K051308	P MTF 323	6, 8, 9
leurological p P MtF347 MtF347										
MAF347			<u>.</u>							
Small Organ [1]	P F347	р МtF347		P MtF347	р М1F347	р МtF347		P MtF347		6,8,9
Moonatal Conhalic			_							
	_									
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
intravascular										
Peripheral Vascular K051308 K051308		P KO51308		р К051308	р К051308	P K051308		P K051308	P MTF323	e, 8, 9
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological) P P P P P P P P P P P P P P P P P P P	Р F347	p MtF347		P MtF347	P MtF347	P MtF347		P MtF347		6,8,9

N = New; P = Previously Cleared by FDA

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D - MTF 356

[8] VPan - MTF 323

[9] XVIEW - MTF 336 Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices 6.081386

						No. of	more of obstations				
Clinical Application	8	Σ	DWP	CWD	Color Doppler	Amplitude	Combined [4]	Color Velocity	Tissue Enhacement Imaging	CnTI	Other
						Doppler		Mapping (TVM)	(TEI)		(specify)
Ophthalmic											
Fetal	đ	۵	۵.		۵	4	۵		P MtF329	d	6,8,9
	MtF329	MtF329	MtF329		MtF329	MtF329	MtF329			MtF346	
Abdominal	ď	C	d		4	d	۵		P MtF329	۵.	6,8,9
	MtF329	MtF329	MtF329		MtF329	MtF329	MtF329			MtF346	
Intraoperative (Abdominal)					٠						
Intraoperative Neurological											
Pediatric	P MtF329	P MtF329	P MtF329		P MrF329	p MtF329	P MtF379		P MtF329	P MIF346	6'8'9
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	р МसF329	р МtF329	р МtF329		P MtF329	P MtF329	p MtF329		P MtF329	P MtF346	6, B, 9
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	۵	۵.	<u> </u>		ď	4	۵		p MtF329	a	6,8,9
	MtF329	MtF329	MtF329		MtF329	MtF329	MtF329			MtF346	

N = New; P = Previously Cleared by FDA

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D ~ MTF 356

[9] XView - MTF 336 [8] VPan - MTF 323

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(K) Number

						Mo	Mode of Operations	ons				
Clinical Application	8	Σ	DWD	CWD	Color Doppler	Amplitude	Combined [4]	Color Velo	city Mapping	Color Velocity Mapping Tissue Enhacement Imaging	CnTi	Other
	'					Doppler		נו	(MVT)	(TEI)		(specify)
Ophthalmic												
Fetal	9	P	4		P K051308	P 0001200	q 00.11307	ط	MtF323	P K051308	P	6,8,9
	KU51308	KU51308	KU51308		ľ	KU51308	KUSTROK				WIT-523	
Abdominal	P K051308	P K051308	р К051308		P K051308	P K051308	Р К051308	<u>a</u>	MtF323	P K051308	р МtF323	6,8,9
Intraoperative (Abdominal)												
Intraoperative Neurological												
Pediatric	P Mt347	P Mtf347	P Mtf347		P Mtf347	P Mtf347	P Mtf347			P MtF347		6,8,9
Small Organ [1]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac (2)												
Transesophageal (Cardiac)	-											
Transesophageal (Non Cardiac)												
Transrectal												
Transvaginal												
Transurethral											,	
Intravascular												
Peripheral Vascular	P .K051308	р КО51308	P K051308		P K051308	P K051308	Р КО51308	Ь	MtF323	P K051308	р MtF323	6,8,3
Laparoscopic												
Musculo-skeletal Conventional [3]												
Musculo-skeletal Superficial [3]												
Other (Urological)	P X051308	р КО51308	P K051308		Р К051308	P K051308	Р К051308	Δ.	MtF323	P K051308	р MtF323	6,8,9

N = New; P = Previously Cleared by FDA

[4] Combined modes are:
B+M+PW+CFM+PD
[6] 3D - MTF 356

[8] VPan - MTF 323

[9] XVIEW - MTF 336 Concurrence of CDRH, Office of Device Evaluation (ODE)

polication B ic P MtF356 al P Attree (Abdominal) attive Neurological	Σ α.	0,710			ľ					
P MtF3S6 P P MtF3S6 ve (Abdominal)	D.	2	CWD	Calar Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	E E	Other (specify)
MtF356 MtF356 We (Abdominal)	D.			†						
al MtF356 ative (Abdominal) ative Neurological	2757464	P P P P P P P P P P P P P P P P P P P		9 23C3+M	P P	P		P MtF356		6,8,9
ative (Abdominal)	MICH356	WITHSOF	-	MILESOB	MILESSE	PILLEGO		P MtF356	Ī	6 8 9
Intraoperative (Abdominal) Intraoperative Neurological	р МtF356	MtF3S6		MtF356	P MtF356	r MtF356				
Intraoperative Neurological										
Pediatric										
Small Organ [1]							-			
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]									1	
Transesophageal (Cardiac)							ļ		:	1
Transesophageal (Non Cardiac)										
Transrectal										;
Transvaginal							Ī			
Transurethral										
intravascular										
Peripheral Vascular P MH356	р МtF356	P MtF356		P MtF3S6	P MtF356	р М1F3S6		P MtF356		6,8,9
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
_	d	d		d :	a.	д.		P MtF356		6, 8, 9
MtF356	MtF356	MtF356		MtF356	MIF356	Mthabb				

N = New; P = Previously Cleared by FDA

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D - MTF 356

[8] VPan - MTF 356

(9) XView - MTF 356

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
Eaglo(k) Number

70 - EC123

							Made of Operations	30%			
				į		TOW	c or oberate				
Clinical Application	6	Σ	GΜd	CWD	Color Doppler	Amplitude	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnJ	Other (specify)
Ophthalmic											
Fetal	P K051308	P K051308	P K051308	 -	Р К051308	P K051308	P K051308	P MtF323	P K051308	P MtF323	6,8,9
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											- 1
Transrectal	<u>a</u>	d	a.		а	Ь	Ь	P MtF323	P K051308	۵	6,8,9
	K051308	K051308	K051308		K051308	K051308	K051308			MtF323	
Transvaginal	Р КО51308	P K051308	Р К051308		P K051308	Р КОS1308	Р КО51308	P MtF323	P K051308	P MtF323	6,8,9
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-sketetal Superficial [3]											
Other (Urological)	Р К051308	P K051308	P X051308		P K051308	P K051308	P KO51308	P MtF323	P K051308	P MtF323	6, 8, 9

N = New; P = Previously Cleared by FDA

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D - MTF 356

[8] VPan - MTF 323

[9] XView - MTF 336

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

70-LA435

						Mode	Mode of Operations	Su			
Clinical Application	æ	Σ	PWO	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTi	Other (specify)
Ophthalmic								:			
Fetal											
Abdominal										1	
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	a.	a.	ъ		Ь	Ы	d		p MTF 329		6, 8, 9, 13
	MtF329	MtF329	MtF329		MtF329	MtF329	MtF329				1
Small Organ [1]	۵.	Ь	a.		۵	n.	۵.		P MTF 329		6, 8, 9, 13
	MtF329	MtF329	MtF329		MtF329	MtF329	MtF329				
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)										1	
Transrectal											
Transvaginal											
Transurethral											
Intravascular										1	
Peripheral Vascular	۵	Ь	ط		a	a.	۵.		P MTF 329		6, 8, 9, 13
	MtF329	MtF329	MtF329		MtF329	MtF329	MtF329				
Laparoscopic											6
Musculo-skeletal Conventional [3]	۵	Ь	а		۵.	مـ	۵		P MTF 329		6, 8, 9, 13
	MtF329	MtF329	MtF329		MtF329	MtF329	MtF329				0
Musculo-skeletal Superficial [3]	۵	Ь	a.		۵	4	a.		P MTF 329		6, 8, 9, 13
	MtF329	MtF329	MtF329		MtF329	MtF329	MtF329			1	
Other (Urological)											
ACH of beneal plantoband - 0 mail - N	4										

N = New; P = Previously Cleared by FDA

[9] XView [1] Small Organs includes Breast, Thyroid

and Testicles
[4] Combined modes are:
B+M+PW+CFM+PD

[13] TP-View

[8] VPan

- QE [9]

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number

70 - LA522

						Mode	Mode of Operations	ns			
Clinical Application	8	Σ	PWD	CWD	Color Doppler	Amplitude	Combined [4]	Calor Velocity	Tissue Enhacement Imaging	CnTI	Other
						Doppler		Mapping (TVM)	(TEI)	-3	(specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological								3		-	
Pediatric	<u> </u>	4	۵		۵	d	d	i	p MTF 323	9	6, 8, 9, 13
	K051308	K051308	K051308		K051308	K051308	K051308			· ·	4
Small Organ [1]	۵	Ь	d .		<u>a</u>	۵	۵		P. MTF 323	9	6, 8, 9, 13
	K051308	K051308	K051308		K051308	K051308	K051308				
Neonatal Cephalic										1	
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral					_						
Intravascular											
Peripheral Vascular	Р	р	p 000013000		P VDE1209	9 KO51308	P KN51308		p MTF323	9	6, 8, 9, 13, 14
lanarosconic	KUS1308	NUSTS08	OUCTCON		DOCTON	accion .	000000				
Musculo-skeletal Coopertional [3]	۵	۵	۵		a.	Ь	ď		P MTF 323	9	6, 8, 9, 13
	K051308	K051308	K051308		K051308	K051308	K051308				
Musculo-skeletal Superficial [3]	۵	۵	a.		а	4	ď		P MTF 323	9	6, 8, 9, 13
	K051308	K051308	K051308		K051308	K051308	K051308				
Other (Urologica!)											
ACT and hence Contract and a second and a	Š										

N = New; P = Previously Cleared by FDA

[1] Small Organs includes Breast, Thyroid

and Testicles

[2] Cardiac is Adult and Pediatric [4] Combined modes are: B+M+PW+CFM+PD

GE [9]

[13] TP-View [9] XV?ew [8] VPan

[14] IMT

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal and (Division Sign-Off)

Radiological Devices 510(k) Number

70 - LA523

						Mod	Mode of Operations	ons			
Clinical Application	8	Σ	DWP	CWD	Color Doppler	Amplitude	Combined [4]	Color Velocity	Tissue Enhacement Imaging	IEUS	Other
					: ,	Dappler		Mapping (TVM)	(TEI)		(specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)				İ							
Intraoperative Neurological											
Pediatric	۵	a	a.		ď	۵	۵	P MtF323	P K051308	Ы	6, 8, 9, 13
	K051308	K051308	K051308		K051308	K051308	K051308			MtF323	
Small Organ [1]	d detaux	P P	q accessor		9	P P	P P P P P P P P P P P P P P P P P P P	P MtF323	P K051308	P P	6, 8, 9, 13
Necostal Centralin	ONETERN	OUCTEUR	NO21200		protect	NOTEDIO	POTTON.	E		777	
אבטומנמו לבטנומונ										İ	
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	р К051308	P K051308	P K051308		P K051308	P K051308	P K051308	P MtF323	P K051308	р MtF3Z3	6, 8, 9, 13, 14
Laparoscopic					-						
Musculo-skeletal Conventional [3]	۵	4	a.		۵	۵	Ь	P MtF323	P K051308	Ь	6, 8, 9, 13
	K051308	K051308	K051308		K051308	K051308	K051308			MtF323	
Musculo-skeletal Superficial [3]	۵	Ь	d		4	Ь	d	p MtF323	р к051308	Ь	6, 8, 9, 13
	K051308	K051308	K051308		K051308	K051308	K051308			MtF323	
Other (Urological)											

N = New; P = Previously Cleared by FDA

[8] VPan [1] Small Organs includes Breast, Thyroid

[2] Cardiac is Adult and Pediatric

[9] XView [13] TP-View

[4] Combined modes are: B+M+PW+CFM+PD

[14] IMT - MTF 331

Concurrence of CDRH, Office of Device Evaluation (OI

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices

510(k) Number ____

70 - LA532

						Moc	Mode of Operations	ions			
Clinical Application	<u> </u>	Σ	DW9.	CWD	Color Doppler	Amplitude	Combined [4]	Color Velocity	Tissue Enhacement Imaging	CnTi	Other
						Doppler		Mapping (TVM)	(TEI)		(specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)								3			
Intraoperative Neurological											
Pediatric	a	a	۵		Ь	Ь	۵	P MtF323	P K051308	c.	6, 8, 9, 13
	K051308	K051308	K051308		K051308	K051308	K051308			MtF323	
Small Organ [1]	_	۵	م		۵.	۵	۵	P MtF323	P K051308	a	6.8.9.13
	K051308	K051308	K051308		K051308	K051308	K051308			MtF323	
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral							İ				
Intravascular				Ì							
Peripheral Vascular	۵	a.	a		_	<u>a</u>	۵	P MtF323	P K051308	۵	6.8.9.13
	K051308	K051308	K051308		K051308	K051308	KD51308			MtF323	
Laparoscopic											
Musculo-skeletal Conventional [3]	d	۵	_		a	۵	<u> </u>		P MtF356	a	6, 8, 9, 13
	MtF356	MtF356	MtF356		MtF356	MtF356	MtF356			MtF356	
Musculo-skeletal Superficial [3]	d	4	4		Ь	d	4		P MtF356	۵	6.8.9.13
	MtF356	MtF356	MtF356	-	MtF356	MtF356	MtF3S6			MtF356	•
Other (Urological)			_								

N = New; P = Previously Cleared by FDA

[1] Small Organs includes Breast, Thyroid

and Testicles
[4] Combined modes are:
B+M+PW+CFM+PD

QE (9)

[8] VPan

[9] XView

[13] TP-View

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal and Radiological Devices $\mathcal{Kos1886}$ (Division Sign-Off)

						Mox	Mode of Operations	suc			
70 - PA122											
Clinical Application	8	Σ	PWD	GW0	Color Doppler	Amplitude	Combined [4]	Color Velocity	Tissue Enhacement Imaging	CnTI	Other
Ophthalmic								fixed Sudden			(shecilly)
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	۵	۵	ď	۵	۵	۵	Ь		P MTF 323		6,9
	K051308	K051308	K051308	K051308	K051308	K051308	K051308				
Small Organ [1]											
Neonatal Cephalic	а	۵	-	_	_	۵	۵		P MTF 323		6 9
	K051308	K051308	K051308	K051308	K051308	K051308	K051308				
Adult Cephalic											•
Cardiac [2]	م	۵	_	۵	۵	4	۵	P MtF356	P MTF 323		6.9
	K051308	K051308	K0S1308	K051308	K051308	K051308	K051308				
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											<i>.</i>
Transurethral											
Intravascular											
Peripheral Vascular	d	م	ط	۵	Ь	۵	۵		P MTF 323		6, 9
	KD51308	K051308	K051308	K051308	K051308	K051308	K051308				
Laparoscopic										-	
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N = New; P * Previously Cleared by FDA [1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[4] Combined modes are: B+M+PW+CW+CFM+PD

[6] 3D - MTF 356

[9] XView - MTF 336

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices 1008/386

70 - PA230

						Mode of C	Mode of Operations				
Clinical Application	æ	Σ	DWD	cwp	Color Doppler	Amplitude	Combined [4]	Color Velocity	Tissue	Chīl	Other
						Doppler (PD)		Mapping (TVM)	Enhacement		(specify)
									Imaging (TEI)		
Ophthalmic											
Fetal											
Abdominal	۵	Ь	۵	۵	Ь	۵	۵	۵	P K051308		6.9
	K051308	K051308	K051308	K051308	K051308	K051308	K051308	MtF323		MtF323	
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic	۵	۵	۵	۵	Ь	۵	۵	a	P K051308	۵	6 9
	K051308	K051308	K051308	K051308	K051308	K051308	K051308	MtF323		MtF323	
Cardiac [2]	۵	۵	_	۵	Ь	۵	Ь	۵	P K051308	۵.	6.9
	K051308	K051308	K051308	K051308	K051308	K051308	K051308	MtF323		MtF323	
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)										ľ	
Fransrectal											
Fransvaginal											
Transurethral											
otravascular											
Peripheral Vascular	d	4	_	a.		۵	d	_	P MtF356	۵	6,9
	MtF356	MtF356	MtF356	MtF356	MtF356	MtF356	MtF356	MtF356		MtF356	
aparoscopic				- 							
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)									:		

N = New; P = Previously Cleared by FDA

[2] Cardiac is Adult and Pediatric

[4] Combined modes are: B+M+PW+CW+CFM+PD

[6] 3D -MTF 356

[9] XView - MTF 336

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number